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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,946	03/24/2000	Frank R. Ruderman	MBHB00-203	1964
20306	7590	05/31/2006	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP			BLECK, CAROLYN M	
300 S. WACKER DRIVE			ART UNIT	
32ND FLOOR			PAPER NUMBER	
CHICAGO, IL 60606			3626	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/534,946

Applicant(s)

RUDERMAN ET AL.

Examiner

Carolyn M. Bleck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-28 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-28 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed on 14 April 2006.

Claims 22-28 and 38 are pending. Claim 38 has been amended.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 22, 24-28, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580) in view of Otvos (6,576,471), Krauss et al. (5,925,229), and Applicant's Background of the Art (page 1 of specification), for substantially the same reasons given in the previous Office Action (mailed 11/2/05). Further reasons appear below.

(A) Claim 38 has been amended to recite a database including test results for "at least 900 cardiovascular patients." Levin discloses a storage means that stores information about test results (col. 5 lines 2-16) in a storage means (see previous Office Action for discussion of this feature. Levin does not expressly disclose the database storing data of at least 900 patients. However, Levin clearly teaches that the pool of patient

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information stored in the database will grow over time (col. 6 lines 3-15). The Examiner respectfully submits that it is well known in the medical database arts to store data for large numbers of patients. For example, it is well known that large hospitals and even small medical practices have databases storing records for more than 900 patients. It would have been obvious at the time of Applicant's invention to include this feature with the motivation of determining the effectiveness of diagnoses and treatments as information is gathered over time based on large numbers of patients (Levin; col. 6 lines 3-15).

(B) Claims 22 and 24-28 have not been amended and are rejected for the same reasons given in the prior Office Action (mailed 11/2/05).

4. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580), Otvos (6,576,471), Krauss et al. (5,925,229), and Applicant's Background of the Art (page 1 of specification) as applied to claim 37, and further in view of Surwit et al. (6,024,699).

(A) Claim 23 has not been amended and is rejected for the same reasons given in the prior Office Action (5/26/06).

Response to Arguments

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5. Applicant's arguments filed 14 April 2006 have been fully considered but they are not persuasive. Applicant's arguments are addressed below in the order in which they appear in the response filed on 14 April 2006.

(A) In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 14 April 2006 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Levin, Otvos, Krauss, and Applicant's Background of the Invention, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (mailed 2 November 2005), and incorporated herein.

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner has provided motivations to combine the applied prior art directly from the references themselves. Note the motivation provided for combining Otvos within Levin given in the Office Action mailed on 2 November 2005 of accurately diagnosing a patient with coronary artery disease by using a comprehensive set of data thus allowing a physician to effectively manage coronary artery disease (Levin; col. 2 lines 15-60) and utilizing subclass information for lipoproteins because subclass information provides a more reliable indicator of a patient's risk to develop coronary heart disease (Otvos; col. 1 lines 55-65). As such, it is respectfully submitted that an explanation based on logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention that supports a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner in both this Office Action and in the previous Office Action.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (571) 272-6767. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (571) 272-6776.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8. Any response to this action should be mailed to:

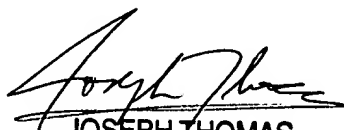
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(571) 273-8300	[Official communications]
(571) 273-8300	[After Final communications labeled "Box AF"]
(571) 273-6767	[Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to the Knox Building, Alexandria, VA.

CB
May 26, 2006


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER